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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/612,591

07/01/2003

Jamieson William MacLean Crawford

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EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/13/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/612,591		CRAWFORD ET AL.	
	Examiner		Art Unit	
	MATTHEW F. DESANTO		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 22-26 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-9, 11-16, 19, 22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szabo et al. (USPN 5,632,732) further in view of Bevilacqua (USPN 5,509,907).

3. Szabo et al. discloses a safety needle device with a shield (40+62) and a channel (72+45) mounted on said shield, and wherein the channel can be moved to different orientations on the shield. Szabo et al. fails to disclose the cannula finger lock.

4. Bevilacqua discloses a needle guard that has severe finger locks to secure the needle to the shield (figure 2, 4, 5, 10) [Bevilacqua discloses reference element 50 which are deflectable cannula fingers which wouldn't permanently lock the needle but instead act as guides and a locking element 60].

5. At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Szabo et al. with the teachings of Bevilacqua because Bevilacqua discloses an easy and effective way to secure the needle to the needle shield to prevent accidental pricking.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 1, 5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, of U.S. Patent No. 7,220,249.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a needle shield device with a needle hub, a needle cannula, a shield and a locking assembly or channel.

8. Claim 1-16, 17, 19, 22-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, of U.S. Patent No. 7,128,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a needle shield device with a needle hub, a needle cannula, a shield and a clip (which is equivalent to the channel in the instant application).

9. Claim 1-16, 17, 19, 22-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,699,217. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim a needle shield device with a needle hub, a needle cannula, a shield and a clip (which is equivalent to the channel in the instant application).

Allowable Subject Matter

10. Claims 10, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Claims 17, 23-25 are in condition for allowance.

Response to Arguments

12. Applicant's arguments filed 07/30/2010 have been fully considered but they are not persuasive.

13. The examiner maintains his rejection because the difference in the claimed invention and the prior art Szabo is a protruding element from the sidewall, which has been shown throughout several pieces of prior art throughout prosecution. The examiner feels that the deflectable finger can be used as a lock as taught in Bevilacqua; or a protruding deflectable finger [as taught in Bevilacqua] could also be added as a centering element to ensure that the needle tip is centered and doesn't accidentally engage the shield thus ruining the needle tip. Both of these modifications to Szabo

provide a benefit and advantage and the addition of adding the protruding deflectable finger would only require routine skill.

14. Bevilacqua discloses reference element 50 which are deflectable cannula fingers which wouldn't permanently lock the needle but instead act as guides and thus provide the benefit as explained above.

i. The examiner feels that adding a cannula lock wouldn't destroy or defeat the purpose of Szabo. One of ordinary skill in the art would understand how to make a cannula lock that could be re-useable or even could lock the needle in the shield before use. The examiner also feels that the cannula finger lock could be used to prevent the needle from piercing the walls of the shield and thus be used as a centering device as well as a locking device. Therefore the examiner feels that one of ordinary skill in the art would be able to modify the device of Szabo to add a cannula finger lock since this element is so well known in the art (see IDS as well as Bevilacqua) and could make the locking or holding element a permanent holding device or a temporary needle holder since the cannula lock could be used before use.

ii. The examiner respectfully disagrees with the interpretation of the 103 Rejection. The examiner feels that Bevilacqua provides proper motivation and a benefit for adding a cannula finger lock to a needle shield since it would prevent the cannula from being accidentally released. One of ordinary skill in the art would understand that the cannula finger lock

would provide an extra benefit to any needle shielding device that lacked such a structure (i.e. Szabo). The examiner also feels that the cannula lock wouldn't be redundant to the device of Szabo since the cannula lock would provide an extra locking element to ensure the needle is locked into the shield. The examiner further relies on MPEP and the recent KSR case when dealing with combining structural elements that are taught in the prior art. See MPEP section 2141 and ["In *United States v. Adams*, . . . [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *Id.* at ___, 82 USPQ2d at 1395. (2) "In *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, . . . [t]he two [pre-existing elements] in combination did no more than they would in separate, sequential operation." *Id.* at ___, 82 USPQ2d at 1395. (3) "[I]n *Sakraida v. AG Pro, Inc.*, the Court derived . . . the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious."] MPEP section 21410.3 - "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple

patents together like pieces of a puzzle.” Id. Office personnel may also take into accounts “the inferences and creative steps that a person of ordinary skill in the art would employ.” Id. at ___, 82 USPQ2d at 1396.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Matthew DeSanto
/Matthew F DeSanto/
Primary Examiner, Art Unit 3763